American Society of Transplant Surgeons

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The Honorable Donald Berwick
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: ASTS Comments on Accountable Care Organization and the Medicare Shared Savings Program

Dear Administrator Berwick:

The American Society of Transplant Surgeons (ASTS) is delighted to have the opportunity to comment on the Accountable Care Organization (ACO) proposed regulations (the Proposed Rule). The ASTS is comprised of over 1700 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to excellence in transplant surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

The health care reform legislation seeks to dramatically increase the formation of integrated and coordinated care providers through the development of ACOs and other models of integrated care. It is our understanding that an ACO will consist of a group of providers (physicians, hospitals, nursing facilities, ancillary care providers and others) that create an organized delivery system whose objective is to achieve cost savings and improve quality. The Patient Protection and Affordable Care Act (Affordable Care Act or "ACA") enables ACOs to share in Medicare savings that they achieve, provided certain thresholds and other requirements are met.

Based on widespread provider reaction to the Proposed Rule, it appears that CMS may wish to reconsider a number of the Proposed Rule's central provisions. More specifically, there has been significant controversy over provisions in the Proposed Rule that require ACOs to incur financial risk relatively quickly (within three years). Many of those in a position to establish ACOs have objected to CMS' proposal to notify an ACO of the Medicare beneficiaries assigned to it only after the conclusion of the contract year. In addition, many have objected to the significant start-up and ongoing operational costs imposed by the Proposed Rule, especially for electronic health record and other information technology.

While these issues are critical to the future success of the ACO program, we do not believe that we, as transplant surgeons, are in a position to offer a unique perspective on these issues. Accordingly, with respect to the broad policy issues implicated by the Proposed Rule, we endorse the comments submitted by the American College of Surgeons. The comments below focus on particular interests of ASTS and its members—continued access to, and quality of , transplantation.

I. Required Inclusion of Transplant Centers in ACO Networks

While, under the ACA, a Medicare patient assigned to an ACO retains the right to obtain care (including transplantation-related services) outside of the ACO network of providers, transplant patients may be dissuaded in a myriad of ways from even considering transplantation. Dissemination of full and accurate information regarding the availability, benefits, and risks of transplantation is necessary to ensure that Medicare and other ACO patients are fully informed of their options, and ACOs may have little incentive to ensure that their patients are fully informed in this regard, especially if a transplant center is not included in the ACO network.

Renal transplantation remains one of the few truly cost-saving therapies that offer superior clinical outcomes to dialysis, and it appears that other transplants (heart, liver) may be cost-effective, given their impact on patient survival; however, these cost savings may not be immediate, and, for that reason, ACOs likely will have a significant incentive to limit access to transplantation for their patients.

For these reasons, we recommend that CMS require ACOs to state specifically in their applications the processes that will be used to assure that Medicare patients have access to relatively costly but medically necessary procedures, such as transplantation. In addition, we urge CMS to monitor access to transplantation carefully for Medicare patients assigned to ACOs. We also recommend that CMS ensure that the number of potential transplant recipients (for example, patients with End Stage Renal Disease) assigned to ACOs is not disproportionate.

II. Quality Measures

Under the Proposed Rule, an ACO would be required to report on 65 quality measures, a number of which are not currently reportable under any of the quality reporting incentive programs established by CMS for various types of providers. We are aware that many providers contemplating the establishment of ACOs believe that these measures impose too great an administrative burden on ACOs and that the costs of collecting data on such a broad set of measures is likely to be prohibitive, especially during the start-up phase.

While we do not disagree with this critique, our concerns are with the proposed quality measures are quite different. Since ACOs will share in a portion of savings on ACO-assigned Medicare beneficiaries, ACOs clearly have a strong financial incentive to skimp on the medical care provided to these patients. In addition, because savings are determined on the basis of the contract year, ACOs likely will have little incentive to facilitate the provision of relatively high cost procedures, such as transplantation, based on long term savings (e.g. cost savings

attributable to the cessation of renal dialysis for renal transplant patients). For these reasons, the primary objective of the quality measures should be to assure that ACO patients continue to receive medically necessary care.

In our view, the quality measures set forth in the Proposed Rule fail to achieve this objective. In fact, there is not a single quality measure in the Proposed Rule related to transplantation. Thus but for malpractice concerns, an ACO could establish processes and procedures that strongly dissuade Medicare patients from considering transplantation as an option or that refer patients to transplant centers based solely on the costs of care. For this reason, we strongly suggest that CMS reevaluate the proposed quality measures and to include some measure of access to specialty care (including transplantation) among the ACO quality measures.

III. **Proposed Beneficiary Assignment Rules**

Under the Proposed Rule, a Medicare beneficiary would be assigned to an ACO if (a) the beneficiary's primary care physician (defined as a physician with a specialty designation of internal medicine, general practice, family practice, or geriatric medicine) is an ACO physician; and (b) that ACO primary care physician is the primary care physician who provides the plurality of primary care services to the Medicare beneficiary during the contract year. Thus, under the Proposed Rule, primary care services provided by specialists, including transplant surgeons, are entirely irrelevant in determining beneficiary assignment to ACOs.

This patient assignment methodology ignores the fact that, for Medicare beneficiaries with organ failure, specialists –and not physicians such as family practitioners, internists, and gerontologists—function as the primary care provider. For example, a cardiologist may serve as a heart failure patient's primary care physician, and a nephrologist may serve as the primary physician for a renal failure patient who is on dialysis. Likewise, transplant physicians/surgeons/programs serve as the medical home for transplant recipients and potential recipients. In light of the need for specialists to remain actively involved in the ongoing management of patients with complex conditions, we believe that the patient's assignment to an ACO should take into account primary care services provided by specialists.

However, **if** the patient assignment rule set forth in the Proposed Rule is retained, we urge CMS to give additional consideration to the role that physician specialists play in coordinating care and achieving savings for patients with acute conditions, such as organ failure. ACOs can be expected to have a significant financial incentive to limit referrals to specialists, and none of the quality or other provisions of the Proposed Rule appear to preclude primary care physicians, who will be held accountable for the cost and quality of their assigned Medicare patients, from limiting referrals to specialists in order to achieve savings targets established by the ACO. For this reason, if the proposed patient assignment rules are retained in the final ACO rule, that rule should also include a provision requiring the ACO to monitor primary care physicians' referral patterns to ensure that medically necessary services are not denied to Medicare patients with cancer and other potentially critical conditions

IV. **Impact on Teaching Hospitals**

We are also concerned about provisions in the Proposed Rule that may dissuade ACOs from fully utilizing the capabilities of academic medical centers. If, as CMS proposes, ACO performance, and the calculation of shared savings, takes into account graduate medical education (IME) payments and disproportionate share (DHS) payments made to hospitals to which ACO patients are referred, ACOs will have a significant financial incentive to refrain from referring ACO Medicare beneficiaries to academic medical centers and other high quality institutions that commonly receive IME or DSH payments. Many of these institutions are the very hospitals that are in the best position to save money and improve quality through better care coordination for both Medicare and Medicaid patients, and many such institutions are those most likely to house transplant centers. For these reasons, we request CMS to reconsider its proposal with respect to the treatment of IME and DSH payments and to remove these payments from the calculation of performance year expenditures.

CMS has expressed some reservations about the legality of removing IME and DSH payments from the calculation of performance year expenditures. However, Congress did not specifically require the inclusion of IME and DSH payments in the calculation of performance year expenditures. Moreover, as CMS has noted, there appears to be no doubt about the legality of removing these expenditures from the calculation of the ACO benchmark. A good argument can be made that removing these payments from the benchmark would be inappropriate unless the expenditures are likewise removed from the performance expenditure calculation as well, and that, therefore, CMS has the discretion to make this change to the Proposed Rule.

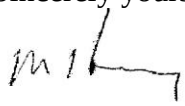
IV. **Transplant Centers as Models for ACOs**

ACOs likely will share a number of characteristics with transplant centers. For example, transplant centers routinely provide multidisciplinary care, report outcomes in a transparent manner, provide care coordination, and function as "medical homes" that manage care (including emergency room visits).

We believe that a number of lessons can be learned from the transplant center experience that may be useful to CMS in drafting the final ACO regulations. For example, a comprehensive system has been developed for measuring the quality of care delivered by transplant centers (both in terms of process and in terms of outcomes), and an equally comprehensive system has been developed for making this information available to the public. Under this system, extensive outcome and other data are reported to the Scientific Registry of Transplant Recipients (SRTR) which makes this information public on a transplant-specific basis, which enables prospective patients and their families to obtain relevant quality information in a user-friendly manner. This system of quality control is supplemented by Medicare certification of transplant centers, which relies heavily on OPTN quality standards. It should be noted that the focus on outcomes and on quality assurance processes in transplantation has been on *programs* and not *individual physicians or providers*. We encourage CMS to consider this approach in reevaluating the required ACO quality measures and in designing other ACO requirements.

We appreciate the opportunity to submit these comments and look forward to working with CMS as the ACO and similar programs are developed in the future.

Sincerely yours,



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